

Exhibit 19

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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 413, and 415

(BFD-712-F)

RIN 0938-AE91

Medicare Program; Fee Schedule for
Physicians' ServicesAGENCY: Health Care Financing
Administration (HCFA), HHS.
ACTION: Final rule.

SUMMARY: This final rule sets forth a fee schedule for payment for physicians' services beginning January 1, 1992. Establishment of this fee schedule is required by section 8102(a) of the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1990. This final rule explains which services will be included in the fee schedule and sets forth the formula for computing payment amounts. Application of transition rules during 1992 through 1995 is also described, as well as other adjustments to fee schedule payment amounts.

DATES: These regulations apply to services furnished beginning January 1, 1992. These regulations are effective January 1, 1992.

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FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

Overview

In this final rule, we explain in detail the statutory authority for the physician fee schedule and the regulations under that authority. Addenda to this rule provide technical documentation to the fee schedule tables, tables containing relative values for physician services and geographic practice cost index values, and information to assist readers in obtaining documents referenced in this final rule.

This final rule adds a new 42 CFR part 415 to apply to physicians' services furnished beginning on January 1, 1992. Existing rules pertaining to reasonable charge payment at 42 CFR part 405, subpart E are being amended to reflect the more limited application of reasonable charge principles once the physician fee schedule becomes effective.

The information in this final rule updates the information supplied June 5, 1991 in the proposed rule (56 FR 25792). Elsewhere in the preamble of this final rule, we have summarized and responded to the comments received in response to the proposed rule and the proposed notice concerning "National Standardization of 'Global Surgery' Policy" that was published in the Federal Register on January 8, 1991 (56 FR 899).

To assist readers in referencing sections contained in this final rule, we are providing the following table of contents:

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physician's service were covered under the separate provisions relating to nonphysician practitioners. They noted that it would be inconsistent to pay for the services of a nonphysician practitioner at a reduced percentage if the service is furnished in a nursing home as required by other provisions of the law, but to pay at the full payment amount for a nonphysician practitioner if services are furnished in a physician's office under the supervision of a physician.

They recognized, however, that this policy might lead to payment for the services of nurses, and other medical personnel at the physician rate, while nonphysician practitioners (who may have higher levels of training and skill) are paid at a lower rate. To remedy this possible problem, they proposed to apply physician fee schedule amounts to services furnished personally by physicians, and that payment for services rarely furnished by physicians (such as injections and simple dressing changes) be "primarily comprised of practice expense and malpractice expense." They proposed that we establish criteria that determine which services should be paid on the basis of practice expense and malpractice expense (services that physicians rarely perform) and which services should be paid on the basis of physician work, practice expense, and malpractice expense.

Some commenters indicated that services "incident to a physician's service" fall into two categories:

- Services that require physician work in which a nonphysician (for example, PA or NP) substitutes for the physician in furnishing the work; and
- Services that are ancillary to the work of the physician and do not require the advanced training and skill of a physician or a nonphysician practitioner, but which can be and are typically performed by a registered nurse (RN), licensed practical nurse (LPN), or health assistant (for example, injections and dressing changes that can be performed by an RN or LPN).

The commenters stated that nonphysician practitioners who substitute for physicians should be paid the same amount as physicians for the services they furnish regardless of whether the service is "incident to" a physician's service, or under the nonphysician practitioner coverage provisions, but that when a nonphysician employee of a physician furnishes an ancillary service that does not require the skills of a physician, the payment to the physician should not include the physician work portion of the payment.

Some commenters supported the proposed use of a modifier to identify services furnished by a nonphysician practitioner or nonphysician, but covered as "incident to" a physician service. Other commenters opposed the proposed use of a modifier to identify services furnished by a nonphysician incident to a physician's service when the physician has no contact with the patient. They indicated that this requirement would lead to confusion, paperwork burden, and would invite circumvention, such as a physician stopping by to ask how the patient is feeling.

Response: While we respect the arguments made in regard to this issue, we intend to continue our longstanding policy on "incident to" services as part of the physician fee schedule for the time being. At this time, we have no data on which "incident to" services are being furnished, the frequency of these services, or who is performing them. We believe this information would be essential in order to establish criteria. Moreover, if we established these criteria, we would be concerned whether the statutory methodology for calculating practice expense and malpractice expense would result in appropriate payment for the resources invested in the nonphysician staff who are furnishing these services. We believe this issue of "incident to" services needs to be carefully considered within the context of payment for practice expenses. In addition, at this time we have decided not to require the use of a modifier to indicate that the physician is billing for a service furnished by a nonphysician practitioner or other nonphysician without a physician encounter. We will continue to consider this issue and may selectively test the use of a modifier to determine to what extent physicians bill for services totally furnished by nonphysician employees under the "incident to" provision.

[Physical Presence of a Physician]

Comment: Commenters objected to the current requirement that the physician be physically on the premises in order for the services of a nonphysician employee to be billed as "incident to" a physician's service.

Response: This requirement is a longstanding coverage requirement for which no change was proposed in the proposed rule and for which no change has been made in this final rule.

c. Drugs and injections. We proposed to use a standard method to pay for drugs (\$ 415.34). We proposed to base payment for drugs on 85 percent of the national average wholesale price of the

drug. For high volume drugs, we proposed that payment be limited to the lower of the estimated actual acquisition costs as determined by us and specified in instructions to carriers, or 85 percent of the national average wholesale price (AWP) of the drug.

When a physician provides a visit or other service to a beneficiary and, during the encounter, the beneficiary receives an injection, we proposed no additional payment would be made for the injection. The drug would be paid separately as discussed above.

Under the proposed rule, in unusual circumstances if no evaluation and management service is furnished and the physician bills for the injection, payment for the injection would be based on the RVUs for the applicable injection code.

We proposed to pay separately for chemotherapy infusions and chemotherapy administration into specialized body cavities.

[Payment for Drugs]

Comment: We received a great many comments on this issue, primarily from oncologists indicating that our 85 percent standard was inappropriate. The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP—particularly multi-source drugs where others were not discounted. Other commenters suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not. The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs.

Also, a number of comments from the oncologists indicated that we should use an add-on to cover the cost of breakage, wastage, shelf-life limitations, and inventory costs associated with chemotherapy agents. Some commenters also suggested that this add-on payment was needed to account for shortfalls in chemotherapy administration payments. Without adequate compensation, commenters suggested, many physicians would perform the service in hospital outpatient departments at substantially higher costs. Also, some commenters suggested that physicians would refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case, the drugs would not be covered by Medicare since the physician did not incur any costs for the drugs.

Response: After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians, or other providers as appropriate, actually pay for the drugs. Carriers could survey a sample of the physicians who furnish the drugs to obtain cost information. As an alternative, carriers could request that physicians periodically provide cost information when they submit claims for payment for the drugs. For certain types of drugs, such as chemotherapy drugs, there may be significant indirect costs such as inventory costs, waste, and spillage. Carriers may consider these costs, if documented, as part of the acquisition cost of a drug.

For high volume or high cost drugs as determined on a national basis, we may designate certain carriers, which represent different geographic areas of the country, to survey physicians in their area to determine the average cost of the drugs. We will distribute the results of these surveys to all carriers. Carriers will be free to evaluate the results of the surveys and use this information in conjunction with any information they have obtained locally to determine the payment for the drugs in their service areas. The revised payment policy for drugs appears in §§ 405.517 and 415.34 of the final regulations.

(Antigens as Drugs)

Comment: Commenters objected to our considering antigens to be drugs or biologicals, and therefore asked that they be excluded from the fee schedule and paid on a reasonable charge basis. They stated that antigens are covered under section 1861(a)(2)(C) of the Act. Also, they noted that that section of the Act is not identified in the definition of "physicians' services" for fee schedule purposes set forth in section 1848(f)(3) of the Act.

Response: After considering the comment, we agree with the commenters. Thus, we are excluding antigens prepared by one physician for administration by another from the physician fee schedule (CPT codes 95135 through 95170). Carriers will continue to pay for these antigens under the current payment methodology.

(Payment for Injection Administration)

Comment: Commenters objected to the proposed policy for drugs and the related bundling of payment for administration of injections into other medical services furnished at the same encounter as presenting a "double hit". They stated that not only would the physician be paid less than his/her cost for the drug, but also, there would be no payment for the additional service of the injection furnished to the patient. They stated that this approach is inconsistent with payment based on resource costs.

Response: As we indicated in our discussion of payment for drugs, we have revised our proposed payment policy for drugs. With respect to payment for injections, we have decided to pay separately for cancer chemotherapy injections, including intra-muscular, intravenous, intra-arterial, and subcutaneous injections, in addition to the visit furnished on the same day. Commenters made a convincing case that these cancer chemotherapy injections are more complex than other injections incident to a physician's service. Therefore, we will pay for all injection procedures in the CPT range of 90400 through 90549 separately in addition to any visit service furnished. For further information on how to bill for the visit, see the discussion on modifiers that appears in this section of the preamble.

We were not convinced by commenters, however, that other intra-muscular, intravenous, intra-arterial, and subcutaneous injections are sufficiently complex that separate payment should be made for them. Therefore, payment for CPT codes 90782 through 90784 will be included in payment for visits or other procedures that are furnished on the same day.

(Payment for ESRD Drugs)

Comment: Several commenters objected to applying the proposed 85 percent of AWP allowance for drugs to ESRD facilities. They stated that their costs for drugs used to treat ESRD patients are greater than this due to several factors.

Response: We are accepting the commenters' suggestions not to apply the proposed 15 percent reduction of the currently allowed AWP for drugs and to consider their invoice costs in determining allowances for ESRD drugs. Therefore, the new payment allowance will be the lower of the facility's estimated acquisition cost of the drug (for example, as determined by the invoice) or the national AWP of the drug. The program's payment will be subject to the usual Medicare Part B

deductible and coinsurance requirements.

B. Formula for Computing Payment Amounts

Section 1848(a) of the Act specifies that payment for Medicare physicians' services must be based on the lesser of the actual charge or the payment amount computed under the fee schedule. Although the law refers to the fee schedule values as "payment amounts", in fact under the statutory formula the amount paid directly to a physician by Medicare will be 80 percent of the actual charge or 80 percent of the fee schedule payment amount, whichever is less. The beneficiary is required to pay the remaining 20 percent. Throughout this final rule, we have used the terms "fee schedule payment amount," "payment amount," "payment," and "allowed charge" as used in the statute to include the amounts for which both the beneficiary and Medicare are responsible.

Under the formula set forth in section 1848(b)(1) of the Act, payment amounts for particular services under the physician fee schedule will be computed as the product of three factors: (1) A relative value for the service, (2) the GAF for the fee schedule area, and (3) a nationally uniform dollar CF. (Although we generally describe a single nationally uniform CF, different CFs for surgical services and other services may be established as part of the MVPS and annual update process. A discussion of the update process appears in the section on the CF.) This general formula can be expressed as:

$$\text{Payment} = \text{RVU} \times \text{GAF} \times \text{CF}$$

where
 RVU = Total relative value units for the service
 GAF = Total geographic adjustment factor for the fee schedule area
 CF = Uniform national CF
 = Service
 = Fee schedule area

Section 1848(e)(2) of the Act requires the total GAF for a fee schedule area to be the sum of three components, relating to the three components of the total RVU for a service. The three components are:

- (1) Physician work;
- (2) Practice expenses or overhead, such as rent, staff salaries, equipment, and supplies, exclusive of professional malpractice liability insurance costs; and
- (3) Professional liability insurance or malpractice costs.

Section 1848(c)(1) of the Act defines the components of the RVU for a

V. Information Collection Requirements

This final rule contains no information collection requirements. Consequently, this rule need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects**42 CFR Part 405**

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 415

Administrative practice and procedure, Health facilities, Health professions, Medicare, Physicians, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as set forth below:

Subpart E—Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

1. The authority citation for subpart E is revised to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1834(b), 1842 (b) and (h), 1848, 1861 (b) and (v), 1862(a)(1), 1865(a), 1871, 1891, 1896, 1897, and 1899 of the Social Security Act as amended (42 U.S.C. 1302, 1393(b), 1395k, 1395l(a), 1395m(b), 1395n (b) and (h), 1395w-4, 1395x(b) and (v), 1395y(a)(1), 1395cc(e), 1395hh, 1395i, 1395w-w, 1395xx, and 1395zz).

2. In § 405.502, paragraph (f)(2) is revised to read as follows:

§ 405.502 Criteria for determining reasonable charges.

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers

determine the reasonable charge for those services by applying the limits described in paragraph (f)(8) of this section.

3. In § 405.509, a new paragraph (c) is added to read as follows:

§ 405.509 Determining the inflation-indexed charge.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

4. Section 405.517 is added to read as follows:

§ 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter.

(b) *Methodology.* Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spillage.

(c) *Multiple-source drugs.* For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

5. Sections 405.521 through 405.524 are revised to read as follows:

§ 405.521 Services of attending physicians supervising interns and residents.

(a) *Basic rules.* (1) Attending physicians' services furnished to beneficiaries in a teaching setting are covered under Medicare Part B; and (2) The payment for these services is on the same fee schedule basis as other

physician services except in those hospitals that have elected cost reimbursement under paragraph (d)(2) of this section.

(b) *Physician direction requirements*

(1) Payment on the basis of the physician fee schedule applies to the professional services furnished to a beneficiary by the attending physician when the attending physician furnishes personal and identifiable direction to interns or residents who are participating in the care of the patient.

(2) In the case of major surgical procedures and other complex and dangerous procedures or situations, the attending physician must personally supervise the residents and interns whom the physician involves in the care of the patients.

(3) Part B payment may be made for the services of an attending physician who involves residents and interns in the care of a patient only if the physician assumes and fulfills the same responsibilities for this patient as for other paying patients.

(4) The carrying out by the physician of these responsibilities is demonstrated by actions such as: Reviewing the patient's history and physical examination and personally examining the patient within a reasonable period after admission; confirming or revising diagnosis; determining the course of treatment to be followed; ensuring that any supervision needed by the interns and residents is furnished; and making frequent reviews of the patient's progress.

(c) *Billing procedures.* (1) Charges for the services of the attending physician may be billed either directly by the physician or by the hospital under arrangements between the physician and the hospital.

(2) In either case, the amount payable is determined using the same criteria that are used in applying the physician fee schedule to services that the physician furnishes to other patients. (The physician fee schedule rules are set forth in part 415 of this chapter.)

(d) *Payment to the hospital.* (1) For services to a patient that involve the participation of residents or interns, the hospital can receive payment for an appropriate share of the compensation it pays its residents and interns as described in § 413.86 of this chapter.

(2) A hospital with an approved teaching program may elect to receive payment on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of any payment on a reasonable charge or fee schedule basis that might otherwise be payable for these services.

provider settings" means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) HCFA establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.*

Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

§ 415.36 *Payment for drugs incident to a physician's service.*

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

§ 415.38 *Special rules for payment of low osmolar contrast media.*

(a) *General.* Payment for low osmolar contrast media is included in the technical component payment for diagnostic procedures except as specified in paragraph (b) of this section.

(b) *Conditions for separate payment.* For diagnostic procedures furnished to beneficiaries who are neither inpatients nor outpatients of any hospital, separate payment is made for low osmolar contrast media used in intrathecal, intravenous, and intra-arterial injections, if it is used for patients with one or more of the following characteristics:

(1) A history of a previous adverse reaction to contrast material, with the exception of a sensation of heat, flushing, or a single episode of nausea or vomiting.

(2) A history of asthma or allergy.

(3) Significant cardiac dysfunction including recent or imminent cardiac decompensation, severe arrhythmias, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension.

(4) Generalized severe debilitation.

(5) Sickle cell disease.

(c) *Method of payment.* If one of the conditions of paragraph (b) of this section is met, payment is made for low osmolar contrast media as set forth in § 415.36 as a drug furnished incident to a physician's service, subject to paragraph (d) of this section.

(d) *Drug payment reduction.* If separate payment is made for low osmolar contrast media, the payment amount calculated in accordance with § 415.36 is reduced by 8 percent to account for the allowance for contrast

media already included in the technical component of the diagnostic procedure code.

§ 415.40 *Coding and ancillary policies.*

(a) *General rule.* HCFA establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* HCFA establishes uniform national ancillary policies necessary to implement the fee schedule for physicians' services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery, bilateral surgery, split surgical global services, team surgery, and unusual services).

§ 415.42 *Adjustment for first 4 years of practice.*

(a) *General rule.* Except as specified in paragraph (b) of this section, the fee schedule payment amount must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), and occupational therapists (OTs), who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services, as defined in section 1842(l)(4) of the Act, furnished by physicians or to services furnished by physicians, PTs, or OTs in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The "first year of practice" is the first full CY during the first 8 months of which the physician, PT, or OT furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 8 months test.

(2) The "second, third, and fourth years of practice" are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment.* The fee schedule payment for the service of a new physician, PT, or OT is limited to

the following percentages for each of the indicated years:

- (1) First year—80 percent.
- (2) Second year—85 percent.
- (3) Third year—90 percent.
- (4) Fourth year—95 percent.

§ 415.44 *Transition rules.*

(a) *Adjusted historical payment basis.*—(1) *All services other than radiology and nuclear medicine services.* For all physicians' services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by HCFA without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services.* For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services.* For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101-239 and section 4102(g) of Public Law 101-508, adjusted by the update established for CY 1992.

(4) *Transition adjustment.* HCFA adjusts the AHPB for all services by 5.5 percent to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physicians' services other than radiology services.* For physicians' services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 413, and 415

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Medicare Program; Fee Schedule for Physicians' Services

Monday, November 25, 1991

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AMA--American Medical Association
APA--Administrative Procedure Act
ASA--American Society of Anesthesiology
ASC--Ambulatory surgical center
AWP--Average wholesale price
BMAD--[Part] B Medicare Annual Data
CAP--College of American Pathologists
CAT--Computerized axial tomography
CBO--Congressional Budget Office
CF--Conversion factor
CFR--Code of Federal Regulations
CHER--Center for Health Economics Research
CMD--Carrier medical director
CNS--Clinical nurse specialist
CP--Clinical psychologist
CPR--Customary, prevailing, and reasonable
CPT--Current Procedural Terminology, 4th Edition (copyrighted by the American Medical Association)
CRNA--Certified registered nurse anesthetist
CRVS--California Relative Value Studies
CSW--Clinical social worker

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expenses. In addition, at this time we have decided not to require the use of a modifier to indicate that the physician is billing for a service furnished by a nonphysician practitioner or other nonphysician without a physician encounter. We will continue to consider this issue and may selectively test the use of a modifier to determine to what extent physicians bill for services totally furnished by nonphysician employees under the "incident to" provision.

[Physical Presence of a Physician]

Comment: Commenters objected to the current requirement that the physician be physically on the premises in order for the services of a nonphysician employee to be billed as "incident to" a physician's service.

Response: This requirement is a longstanding coverage requirement for which no change was proposed in the proposed rule and for which no change has been made in this final rule.

c. Drugs and injections. We proposed to use a standard method to pay for drugs (s 415.34). We proposed to base payment for drugs on 85 percent of the national average wholesale price of the drug. For high volume drugs, we proposed that payment be limited to the lower of the estimated actual acquisition costs as determined by us and specified in instructions to carriers, or 85 percent of the national average wholesale price (AWP) of the

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drug.

When a physician provides a visit or other service to a beneficiary and, during the encounter, the beneficiary receives an injection, we proposed no additional payment would be made for the injection. The drug would be paid separately as discussed above.

Under the proposed rule, in unusual circumstances if no evaluation and management service is furnished and the physician bills for the injection, payment for the injection would be based on the RVUs for the applicable injection code.

We proposed to pay separately for chemotherapy infusions and chemotherapy administration into specialized body cavities.

[Payment for Drugs]

Comment: We received a great many comments on this issue, primarily from oncologists indicating that our 85 percent standard was inappropriate. The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP--particularly multi-source drugs--while others were not discounted. Other commenters suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not. The bulk of the

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comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs.

Also, a number of comments from the oncologists indicated that we should use an add-on to cover the cost of breakage, wastage, shelf-life limitations, and inventory costs associated with chemotherapy agents. Some commenters also suggested that this add-on payment was needed to account for shortfalls in chemotherapy administration payments. Without adequate compensation, commenters suggested, many physicians would perform the service in hospital outpatient departments at substantially higher costs. Also, some commenters suggested that physicians would refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case, the drugs would not be covered by Medicare since the physician did not incur any costs for the drugs.

*59525 Response: After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs

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revised our proposed payment policy for drugs. With respect to payment for injections, we have decided to pay separately for cancer chemotherapy injections, including intra-muscular, intravenous, intra-arterial, and subcutaneous injections, in addition to the visit furnished on the same day. Commenters made a convincing case that these cancer chemotherapy injections are more complex than other injections incident to a physician's service. Therefore, we will pay for all injection procedures in the CPT range of 96400 through 96549 separately in addition to any visit service furnished. For further information on how to bill for the visit, see the discussion on modifiers that appears in this section of the preamble.

We were not convinced by commenters, however, that other intra-muscular, intravenous, intra-arterial, and subcutaneous injections are sufficiently complex that separate payment should be made for them. Therefore, payment for CPT codes 90782 through 90784 will be included in payment for visits or other procedures that are furnished on the same day.

[Payment for ESRD Drugs]

Comment: Several commenters objected to applying the proposed 85 percent of AWP allowance for drugs to ESRD facilities. They stated that their costs for drugs used to treat ESRD patients are greater than this due to several factors.

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Response: We are accepting the commenters' suggestions not to apply the proposed 15 percent reduction of the currently allowed AWP for drugs and to consider their invoice costs in determining allowances for ESRD drugs. Therefore, the new payment allowance will be the lower of the facility's estimated acquisition cost of the drug (for example, as determined by the invoice) or the national AWP of the drug. The program's payment will be subject to the usual Medicare Part B deductible and coinsurance requirements.

B. Formula for Computing Payment Amounts

Section 1848(a) of the Act specifies that payment for Medicare physicians' services must be based on the lesser of the actual charge or the payment amount computed under the fee schedule. Although the law refers to the fee schedule values as "payment amounts", in fact under the statutory formula the amount paid directly to a physician by Medicare will be 80 percent of the actual charge or 80 percent of the fee schedule payment amount, whichever is less. The beneficiary is required to pay the remaining 20 percent. Throughout this final rule, we have used the terms "fee schedule payment amount," "payment amount," "payment," and "allowed charge" as used in the statute to include the amounts for which both the beneficiary and Medicare are responsible.

Under the formula set forth in section 1848(b)(1) of the Act, payment

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considerable additional costs associated with the use of LOCM since there is little scientific evidence *59558 that the existing contrast product presented any substantial health risk to the great majority of patients.

Based on the findings of studies and the development of criteria by the ACR as to the appropriate usage of LOCM, we now believe that we can establish a national policy on separate payment for LOCM. Since the payment for this product will be made outside of the fee schedule, the \$20 million limitation set forth in section 1848(c)(2)(B)(ii)(II) of the Act does not apply.

It was our intention to establish RVUs for the Level 2 HCPCS code for LOCM (A4648) that would be used to compute payments in all instances meeting one of the payment criteria. Based on the comments received, we have determined that this is not feasible because of differences in the basic drugs in question, different concentrations associated with each drug, and different dosages used for different procedures.

In accordance with the nearly unanimous view of the commenters, we have decided to pay for LOCM, if the patient meets the required criteria, under the standard methodology for payment of a drug furnished incident to a physician's service generally with one additional condition to prevent duplicate payment. That is, we will base payment on the lower of the estimate of the actual acquisition cost (determined based on the carrier survey of the actual invoice price paid by the physician) or the national AWP of the drug less 8 percent.

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ratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies includes a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter.

(b) *Methodology.* Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug.

In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(c) *Multiple-Source drugs.* For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

[56 FR 59621, Nov. 25, 1991]

§ 405.520 Reimbursement for services of interns, residents and supervising physicians: general.

(a) Under the health insurance program, almost all the aged have protection against hospital expenses, and the great majority also have protection against medical expenses. This health insurance coverage is intended to provide a substantial measure of freedom to beneficiaries in selecting hospitals and physicians of their choice. Whatever the choice, beneficiaries, as insured patients, are to be accorded the same status as other insured and paying patients in regard to the hospital and medical care they are provided.

(b) Many beneficiaries will choose to receive the care they need from hospitals with approved graduate medical education programs and from other institutions where services of interns and residents are provided. Many will receive care in these hospitals as patients of physicians who, in turn, will involve interns and residents in the care of their patients. The basis for reimbursement for such services by interns and residents is different from that applicable to such physicians' services.

§ 405.521 Services of attending physicians supervising interns and residents.

(a) *Basic rules.* (1) Attending physicians' services furnished to beneficiaries in a teaching setting are covered under Medicare Part B; and

(2) The payment for these services is on the same fee schedule basis as other physician services except in those hospitals that have elected cost reimbursement under paragraph (d)(2) of this section.